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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/177,814	10/23/1998	TERRY L. GILTON	353OUS(97-12	3621

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EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/177,814	Applicant(s) GILTON, TERRY L.	
	Examiner Nelson Yang	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11 and 13-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 13-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2005 has been entered.
2. Applicant's amendment of claim 1 is acknowledged and has been entered.
3. Applicant's cancellation of claims 30-44, 46, 48-64, 66-74, 105-107 is acknowledged and has been entered.
4. Claims 1, 3-11, 13-29 are currently pending.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 5, 7, 8, 10, 14, 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Knoll [US 5,393,401].

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With respect to claim 1, Knoll teaches a sensor comprising a silicon substrate (column 2, lines 60-62) with ion selective field effect transistors (column 4, lines 35-40) and ion-selective membranes formed in containments on the silicon substrate (column 5, lines 4-15).

7. With respect to claim 5, ion-selective membranes are formed in containments on the silicon substrate (column 5, lines 4-15), and therefore would only extend partially across the substrate.

8. With respect to claims 7, 8, 10, 25-28, Knoll teaches that the enzymes, antibodies microbes or organelles can be immobilized in the membrane (column 5, lines 9-15).

9. With respect to claim 14, Knoll teaches a sensor comprising a silicon substrate (column 2, lines 60-62) with ion selective field effect transistors (column 4, lines 35-40).

10. With respect to claim 29, Knoll teaches that the ion-selective membranes can be protected by another layer of material (column 5, lines 4-9).

11. Claims 1,3, 5, 6-11, 14, 18, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Heller et al [US 5,605,662] in light of Vickers et al [US 5,693,946].

12. With respect to claim 1, Heller et al teach a device having a matrix of addressable microscopic locations on its surface, where each individual micro-location is able to electrocially control and direct the transport and attachment of specific binding entities to itself (column 5, lines 35-43). Each micro-location comprises a permeation layer, an attachment layer, and a binding entity layer (fig. 2, column 10, lines 59-67). The permeation and attachment layers are porous (column 15, lines 1-6). Detection may be performed by CCD detectors associated directly with the device in a sandwich arrangement (column 20, lines 45-50). One of ordinary skill in the

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art would realize that CCD detectors comprise FETs, as evidenced by Vickers et al (column 4, lines 1-10).

13. With respect to claim 3, the microlocation are part of microcapillaries (column 24, lines 15-20).

14. With respect to claim 5, the permeation layer constitutes only part of each microlocation (fig. 6), and therefore would only extend partially across the substrate.

15. With respect to claim 6, microlocations were used for negative control for nonspecific binding (column 25, lines 1-5), which would render these microlocations as control columns.

16. With respect to claims 7-11, the binding entity layers are located underneath the permeation and attachment layers, and may contain antibodies (fig. 6, column 11, lines 15-40).

17. With respect to claim 14, detection may be performed by CCD detectors associated directly with the device in a sandwich arrangement (column 20, lines 45-50). One of ordinary skill in the art would realize that CCD detectors comprise FETs, as evidenced by Vickers et al (column 4, lines 1-10).

18. With respect to claims 18, 22-24, the device comprises microelectrodes located at the ends of the permeation layers (fig. 6), and the opposite charge of the specific binding entities can be applied to a specified microelectrode while the other microelectrodes are maintained at the sample charge (column 15, lines 55-65), resulting electrodes that are anodes or cathodes.

19. Claims 1, 3-11, 15, 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Roberts et al [US 5,958,791].

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With respect to claim 1, Roberts teach a test device for detecting or determining an analyte in a test solution divided into separate compartments by a partition extending across the entire width of the array for the control solution and the test mixture (column 15, lines 1-10), and comprising an absorbent material comprising a porous material (column 12, lines 4-15) in each of the compartments (column 15, lines 45-50). Roberts further teach an electrochemical measurement portion wherein the absorbent material is in contact with first conductors and second conductors which are connected to a potentiostat or electroanalyzer (column 15, lines 18-32).

20. With respect to claim 3, the channels function by capillary action by utilizing the absorbent material (column 15, lines 45-55).

21. With respect to claims 4-5, the absorbent material comes into contact with the conductors, and traverses the substrate, but does not extend across the entire substrate (column 15, lines 18-32, fig. 1)

22. With respect to claim 6, Roberts et al teach that the test device is divided two channels, a control channel and a test channel (column 15, lines 5-10).

23. With respect to claims 7-11, Roberts et al teach the presence of competitive binding and measurement portions situated at a predetermined distance from the end of the absorbent material (fig.1, column 15, lines 5-17).

24. With respect to claim 15, Roberts et al teach a voltage application component and a current detection component (column 27-28, example 2).

25. With respect to claims 25-28, Roberts et al teach that the capture portion can comprise antigens and antibodies (column 9, lines 45-50), nucleic acids (column 10, lines 50-65).

26. Claims 1, 2, 4,5, 7-9, 13, 16-20, 22-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Burns et al [US 6,379,929].

With respect to claim 1, Burns et al teach a device with isothermally regulated reaction chambers (column 3, lines 45-50) and porous gel columns of micromachined channels for gel electrophoresis (column 57, lines 33-44) etched on silicon chips (column 57, lines 22-38) as well as temperature sensors (column 62, lines 15-20).

27. With respect to claim 2, the channels are capable of capillary gel electrophoresis (column 57, lines 45-50), and therefore would be capillary columns.

28. With respect to claims 4, 5, the channels linearly traverse the chip, but only extend partially across the substrate (fig. 2b).

29. With respect to claims 7-9, 25-27, Burns et al teach that following separation of amplification products, a probe conjugated to an antibody may be brought into contact with the amplified marker sequence (column 53, lines 30-40).

30. With respect to claim 13, Burns et al teach that the silicon chip comprise temperature sensors (column 62, lines 15-20).

31. With respect to claim 16, a microprocessor may be on-wafer (column 32, lines 45-52).

32. With respect to claim 17, the output information is stored by the microprocessor (column 32, lines 45-52). The microprocessor would thus act as a memory device.

33. With respect to claims 18-20, Burns teach that the device comprises a migration facilitator such as a pump (column 35, lines 50-55), and sealed valves for flow control (column 44, lines 9-40).

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34. With respect to claims 22-24, electrodes are located at either end of the channels (column 31, lines 55-65) for purposes of electrophoresis (column 32, lines 65-67), which would require electrodes at one end of the channels to be anodes, and electrodes at the other end to be cathodes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al [US 6,379,929] in view of Dubrow [US 5,948,227].

36. Burns et al teach a device with isothermally regulated reaction chambers (column 3, lines 45-50) and porous gel columns of micromachined channels for gel electrophoresis (column 57, lines 33-44) etched on silicon chips (column 57, lines 22-38) as well as temperature sensors (column 62, lines 15-20). Burns further teach that the device comprises a migration facilitator such as a pump (column 35, lines 50-55), and sealed valves for flow control (column 44, lines 9-40). Burns et al fail to teach that the migration facilitator comprises a vacuum source.

Dubrow, however, teaches a vacuum source (column 7, lines 1-10) and further teaches that the vacuum source allows a solution to be driven into a capillary channel (column 7, lines 1-10).

Therefore it would have been obvious in the device of Burns et al to have a vacuum source, as suggested by Dubrow, in order to drive a solution into the capillary channels.

Response to Arguments

37. Applicant's arguments with respect to claims 1, 3-11, 13-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

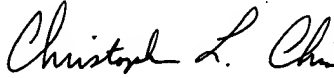
38. No claims are allowed.

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

40. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641


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4/29/05